

Sub E1
D¹
1. (Amended) A liquid pharmaceutical formulation comprising human interferon- β as an active ingredient in a concentration of up to 25×10^6 u/ml and a buffer for buffering in a pH range of 5 to 8, with the proviso that the formulation does not contain human serum albumin, or any acidic amino acids, arginine or glycine in amounts of between 0.3 and 5% by weight, wherein after storage for 3 months at 25°C, stability of in vitro biological activity of the formulation is at least 80% of an initial biological activity.

2. (Amended) The liquid formulation according to Claim 1, comprising a buffer for buffering in a pH range of 6 to 7.2.

D²
3. (Amended) A liquid formulation comprising human interferon- β as the active ingredient, a buffer for buffering a pH in a range of 5 to 8, and at least one amino acid, with the proviso that the formulation does not comprise any acidic amino acids, arginine or glycine in amounts of between 0.3 and 5% by weight, wherein after storage for 3 months at 25°C, stability of an in vitro biological activity of the formulation is at least 80% of an initial biological activity.

4. (Amended) The formulation according to Claim 1, wherein the interferon- β is a glycosylated interferon- β .

5. (Amended) The formulation according to Claim 2, wherein the interferon- β is recombinantly produced in CHO cells.

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6. (Twice Amended) The formulation according to Claim 1, wherein the buffer is in a concentration of 10 mmol/l to 1 mol/l.

7. (Twice Amended) The formulation according to Claim 1, wherein the buffer is selected from the group consisting of a phosphate, a citrate and an acetate buffer, and a combination thereof.

8. (Amended) The formulation according to Claim 7, wherein the buffer comprises a phosphate/citrate buffer.

9. (Twice Amended) The formulation according to Claim 1, wherein the pH is between 6 and 7.2.

10. (Amended) The formulation according to Claim 3, wherein the formulation does not contain human serum albumin.

11. (Twice Amended) The formulation according to Claim 1, wherein the active ingredient is free from human or animal polypeptides.

12. (Twice Amended) The formulation according to Claim 1, wherein the formulation is free from surfactants.

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13. (Twice Amended) The formulation according to Claim 1, wherein after storage of the formulation for 6 months at 25°C, the formulation is chemically stable.

14. (Twice Amended) The formulation according to Claim 1, wherein after storage of the formulation for 6 months at 25°C, the formulation is physically stable.

15. (Twice Amended) The formulation according to Claim 1, further containing at least one amino acid.

16. (Twice Amended) The formulation according to Claim 3, wherein the formulation contains methionine.

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17. (Amended) The formulation according to Claim 16, wherein the methionine is present in a concentration of 0.1 to 4 mmol/l.

18. (Twice Amended) The formulation according to Claim 1, further comprising an ingredient for adjusting tonicity.

19. (Twice Amended) The formulation according to Claim 1, comprising a thickener for increasing viscosity.

20. (Twice Amended) The formulation according to Claim 1, further containing at least one physiologically acceptable preservative.

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21. (Twice Amended) A pharmaceutical composition comprising a liquid formulation according to Claim 1, and a pharmaceutically acceptable carrier.

22. (Amended) The pharmaceutical composition according to Claim 21 in a form suitable for oral, parenteral or ophthalmological administration.

D3
23. (Twice Amended) The pharmaceutical composition according to Claim 21, wherein the composition is in the form of a unit containing 1 to 25×10^6 IU of interferon- β .

D4
25. (Amended) A process for stabilizing a liquid formulation comprising human interferon- β as the active ingredient and a buffer for buffering in a pH range of 5 to 8, said process comprising adding a stabilizing amount of at least one amino acid, provided that the amino acid is not an acidic amino acid, arginine or glycine in an amount of between 0.3 to 5% by weight of the formulation, with the further proviso that human serum albumin is not present in the formulation.

26. (Amended) The process according to Claim 25, wherein the stabilizing comprises increasing at least one of the long-term stability of the in vitro biological activity, the chemical stability and the physical stability of the formulation.